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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dennis Cherok et al.
Serial No.:	09/661,623
Confirmation No.:	8712
Filed:	September 14, 2000
For:	IMPLANTABLE PROSTHESIS
Examiner:	Matthews, William H.
Art Unit:	3738

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION OF STEPHEN N. ELDRIDGE UNDER 37 CFR § 1.132

I, Stephen N. Eldridge, declare as follows:

1. I received a Masters of Science degree in Animal Pathology from the University of Rhode Island (1982). I hold a Bachelor of Science degree in Biology from Edinboro State University, Edinboro Pennsylvania (1979).

2. Since 1986, I have been employed by several divisions of C.R. Bard, Inc., which is the assignee of the above-identified patent application. From 1986 to 1995, I worked for Bard Vascular Systems (formerly known as Bard Cardio-Surgery) conducting research and development of vascular grafts, including protein coating of vascular grafts. In the early 1990's, I became involved in the research and development of soft tissue repair prosthetics, including mesh repair fabrics. In 1995, I transferred to Davol, Inc., another division of C.R. Bard, where I have continued my work on the research and development of soft tissue repair prosthetics. From 1995 to 1997, I was a senior development engineer at Davol responsible for the development and commercialization of soft tissue repair products. Since 1997, I have been the Manager of Research & Development for Hemostasis and Soft Tissue Repair Products at Davol. I am responsible for supervising a team of development engineers involved with the R&D and commercialization of soft tissue repair prosthetics.

3. Since 1992, my primary work has focused on the interaction of biomaterials with tissue, and more specifically on the ingrowth of tissue to biomaterials and the prevention of tissue ingrowth and subsequent adhesions to biomaterials.

4. To date, I am an inventor on seven (7) U.S. patents issued to C.R. Bard, and an inventor on several pending U.S. patent applications.

5. I am familiar with the level of knowledge possessed by those of ordinary skill in the art of soft tissue repair prosthetics as of the filing date of the present application. My comments below are based upon my appreciation of industry knowledge as of that timeframe.

6. I understand that the Examiner in charge of handling the above-identified application has rejected the claims as being unpatentable over Mulhauser (U.S. Patent No. 5,766,246). I have reviewed this reference, the pending independent claims and the Final Office Action of October 31, 2003. I respectfully disagree with the Examiner's position relative to the reference, as detailed below.

7. Mulhauser is directed to an implantable prosthesis 10 having a mesh layer 12 and a semi-rigid ring 14 supporting the mesh layer. (Mulhauser, Col. 3, lines 39-49). As shown in Fig. 2(b), the ring may be configured to extend over the mesh layer at the peripheral edge of the mesh layer.

8. I understand the Examiner has taken the position that the Mulhauser ring 14 is a barrier to adhesions with tissue and muscle, forming an edge barrier. More particularly, I understand the Examiner to maintain that the ring 14 is an adhesion resistant barrier on the basis that it may be made of silicone material. I do not find anything in Mulhauser to suggest the ring as being adhesion resistant. Mulhauser does not teach or suggest that the ring 14 has any type of adhesion inhibiting properties. Mulhauser only indicates that the ring 14 may be formed from a polypropylene or silicone material, or that the ring may be formed by hot or cold forming a ring-shaped depression in the mesh layer itself. (Mulhauser, Col. 4, lines 60-65).

9. The adhesion resistant properties of a soft tissue repair prosthesis are affected by various factors including the surface texture and pore size of the material that forms the prosthesis or portions of the prosthesis. Thus, a prosthesis may be either resistant to the formation of adhesions or promote tissue ingrowth and adhesions depending upon the particular structural characteristics of its material. For example, a prosthetic material, including silicone, having a surface texture or porosity of approximately 10μm or more is not adhesion resistant, but rather is susceptible to adhesions with tissue or muscle.

10. Mulhauser provides no teaching or suggestion as to any structural characteristics of a silicone ring that would determine its adhesion resistant properties. As indicated above, Mulhauser discloses only that the ring may be formed from a silicone material. However, the surface texture and porosity of a silicone ring (as well as a molded polypropylene ring) can vary depending on the specific design parameters of the mold used to form the ring. Therefore, a molded silicone ring can promote tissue ingrowth and adhesions with tissue and muscle. Thus, the fact that the Mulhauser ring may be made from a silicone material does not lead me to the conclusion that the ring inhibits adhesions to tissue and muscle. I also believe that one of ordinary skill in the art would not consider the Mulhauser ring, even if formed of silicone material, as necessarily being resistant to tissue ingrowth and adhesions to tissue and muscle.

11. I understand the Examiner has taken the position that silicone does not promote tissue ingrowth based on the Mulhauser teaching of an adhesion barrier 36 that may be formed of a silicone material. I respectfully disagree. An adhesion resistant barrier layer, such as may be employed on the Mulhauser prosthesis, requires a microporous structure having a surface texture or porosity that is less than 10μm. This is not an inherent property of the material itself, but varies depending upon the structure formed with the material, whether it is silicone or other material. Concerning the barrier 36, Mulhauser discloses using Silastic® Rx Medical Grade Sheeting (Platinum Cured), which is a particular silicone sheet product fabricated to provide adhesion resistant properties. Thus, the fact that a silicone elastomer may be employed as a barrier material does not support a conclusion that any structure formed from a silicone

elastomer, such as the Mulhauser ring, is necessarily adhesion resistant. I also believe that one of ordinary skill in the art would recognize that an adhesion resistant barrier layer requires a microporous structure and that structures formed from a silicone elastomer are not necessarily microporous and adhesion resistant.

12. I understand the Examiner also contends that Mulhauser teaches a peripheral barrier having an outer margin that is melted and resolidified. I respectfully disagree. Although Mulhauser indicates that the ring may be formed by hot forming a ring-shaped depression in the mesh sheet, this does not necessarily involve any melting and resolidifying of the mesh material. Nevertheless, even when assuming that hot forming does involve some degree of melting and resolidifying of the outer margin, it does not necessarily follow that the entire thickness of the outer peripheral edge would be adapted to inhibit the formation of adhesions thereto. Rather, the degree of melt would vary depending on a number of factors including die design, applied pressure, dwell time, temperature (heated die process) and frequency (sonic weld process). Additionally, it is unclear to me as to where the ring-shaped depression would even be formed (i.e., at the outer peripheral edge or spaced inward from the peripheral edge) on the fabric layer. Thus, I believe that hot or cold forming a ring-shaped depression does not necessarily result in the entire thickness of the outer peripheral edge being adapted to inhibit adhesion formation. I also believe that one of ordinary skill in the art would recognize that hot or cold forming a ring-shaped depression does not necessarily result in the entire thickness of the outer peripheral edge being adapted to inhibit adhesion formation.

13. I understand the Examiner further contends that the figures of Mulhauser support his position that the ring inhibits tissue ingrowth on the basis that the figures show a solid ring lacking interstices. I respectfully disagree. Nothing in the figures provides any indication that the ring is adhesion resistant. As indicated above, the adhesion resistance of a material implanted in a body depends on the surface texture and porosity of the material and that tissue ingrowth can occur when the surface texture or porosity is approximately 10μm or more. This amount of surface texture and porosity is microscopic and undetectable with the naked eye. Thus, the fact that interstices are not illustrated in the Mulhauser drawings does not lead me to

conclude that the ring is resistant to tissue ingrowth or adhesions. I also believe that one of ordinary skill in the art would not consider the ring to be adhesion resistant based on the drawings.

14. For the foregoing reasons, I find no support for the Examiner's position that the Mulhauser ring 14, even if formed from a silicone elastomer or hot formed as a depression, inhibits the formation of adhesions with tissue or muscle. More particularly, Mulhauser fails to teach or suggest any structural characteristics that affect the adhesion resistant properties of the ring 14. I also believe that one of ordinary skill in the art would not consider the Mulhauser ring 14, even if formed of a silicone elastomer or hot formed as a depression, as necessarily inhibiting the formation of adhesions with tissue or muscle.

I, the undersigned, declare that all statements herein of my own knowledge are true and that all statements made on information and belief are believed to be true. And further, that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of title 18 of the United States code and that such willful false statements may jeopardize the validity of this document and any patent which may issue from the above-identified patent application.

2/24/04
Date

Stephen N. Eldridge